IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

JOAN HAMMOND ROBINSON,

Plaintiff,

vs. CASE NO.: 3:07-cv-00450-HLA-HTS

MERCK & CO., INC.; PFIZER, INC.; PHARMACIA CORPORATION, a wholly-owned subsidiary of PFIZER, INC.; PHARMACIA & UPJOHN COMPANY, LLC, a wholly-owned subsidiary of PHARMACIA CORPORATION; G.D. SEARLE LLC (f/k/a G.D. SEARLE & CO.); and MONSANTO COMPANY,

Defendants.
_____/

DEFENDANTS PFIZER INC., PHARMACIA CORPORATION, PHARMACIA & UPJOHN COMPANY LLC, AND G.D. SEARLE LLC'S ANSWER AND DEFENSES AND JURY DEMAND

Defendants Pfizer Inc. (incorrectly captioned as "Pfizer, Inc.") (hereinafter "Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company[1]) (hereinafter "Pharmacia"), Pharmacia & Upjohn Company LLC (incorrectly captioned as "Pharmacia & Upjohn Company, LLC"), and

[1] Plaintiff's Complaint names "Monsanto Company" as a defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Bextra® or Celebrex®. Given that Plaintiff alleges in her Complaint that Monsanto Company was involved in developing Bextra® or Celebrex®, *see* PLAINTIFF'S COMPLAINT at ¶ 14, 17, and 18, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

G.D. Searle LLC (hereinafter "Searle") (collectively referred to herein as "Defendants") respond to the complaint as follows:

I.
PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® or Bextra®. Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex® or Bextra®.

This preliminary statement is incorporated by reference in its entirety in response to each and every Paragraph of the Complaint.

II.

ORIGINAL ANSWER

1. Defendants admit that Plaintiff purports to bring this action and seeks damages in excess of $15,000, but deny that there is any legal or factual basis for the purported causes of action and/or damages sought by Plaintiff as a result of Celebrex® and/or Bextra® use.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph of the Complaint except that Defendants are informed and believe that Plaintiff is a citizen of Florida.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations of Plaintiff's medical condition or whether she took Celebrex® or Bextra®, and therefore deny the same. Defendants deny that Celebrex® or Bextra® caused Plaintiff injury or damages and deny the remaining allegations in this Paragraph of the Complaint.

4. The allegations contained in this Paragraph of the Complaint are not directed toward the Defendants and, therefore, no response is required.

5. The allegations contained this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required.

6. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants deny the remaining allegations in this Paragraph of the Complaint.

7. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same, but admit that Pfizer is authorized to do business in Florida. Defendants deny the remaining allegations in this Paragraph of the Complaint.

8. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey.

9. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same, but admit that Pharmacia is a wholly-owned subsidiary of Pfizer.

10. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Celebrex® or Bextra®, and deny that it is a proper party in this suit. Defendants deny all remaining allegations in this Paragraph of the Complaint. The response to this Paragraph of the Complaint regarding Pharmacia & Upjohn is incorporated by reference in response to each and every Paragraph of the Complaint referring to Pharmacia & Upjohn and/or Bextra Defendants.

11. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Celebrex® or Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this Paragraph of the Complaint.

12. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same. Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Celebrex® or Bextra®, and deny that it is a proper party in this suit. Defendants deny all remaining allegations in this Paragraph of the Complaint.

13. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois and that it is presently a wholly-owned third tier subsidiary of Pharmacia Corporation, which in turn is a wholly-owned subsidiary of Pfizer Inc. Defendants deny the remaining allegations in this Paragraph of the Complaint.

14. Defendants admit that, in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is a

corporation existing under the laws of Delaware. The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex® or Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold, resold, marketed, or distributed Celebrex® or Bextra®, the 2000 Monsanto is not a proper party in this matter. Defendants deny all remaining allegations in this Paragraph of the Complaint. The response to this Paragraph of the Complaint regarding Monsanto is incorporated by reference in response to each and every Paragraph of the Complaint referring to Monsanto and/or Celebrex Defendants.

15. The allegations in this Paragraph of the Complaint assert a legal conclusion to which no response is required. To the extent a response is required, Defendants deny that Defendant Pharmacia & Upjohn Company LLC ever designed, produced, manufactured, marketed, sold, resold or distributed Celebrex® or Bextra®, and deny that it is a proper party in this suit. Defendants deny the remaining allegations in this Paragraph of the Complaint.

16. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material" and therefore deny the same. Defendants admit that during certain periods of time Pfizer and Pharmacia co-promoted and marketed Bextra® throughout the United States, including Florida, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. . Defendants deny the remaining allegations in this Paragraph of the Complaint.

17. The allegations in this Paragraph of the Complaint assert a legal conclusion and therefore no response is required. To the extent a response is required, Defendants state that

2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex® or Bextra® and therefore deny that the 2000 Monsanto is a proper party to this suit. Defendants deny the remaining allegations in this Paragraph of the Complaint.

18. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material" and therefore deny the same. Defendants admit that during certain periods of time Pfizer and Pharmacia co-promoted and marketed Celebrex® and Bextra® in the United States, including Florida, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that during certain periods of time Celebrex® and Bextra® were manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® and Bextra® in the United States, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with its approval by the FDA. Defendants state that the 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex® or Bextra®, and therefore deny that Monsanto is a proper party to this suit.. Defendants deny the remaining allegations in this Paragraph of the Complaint.

19. The allegations contained in this Paragraph concerning Vioxx, aspirin, naproxen and ibuprofen are not directed toward the Defendants and, therefore, no response is required. Defendants admit that, as stated in the package inserts approved by the United States Food & Drug Administration ("FDA"), Celebrex® and Bextra® are in a class of drugs that is,

at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Defendants deny the remaining allegations on this Paragraph of the Complaint.

20. The allegations contained in paragraph 20 are not directed towards Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

21. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

22. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

23. The allegations contained in this Paragraph of the Complaint concerning Merck and "other pharmaceutical companies" are not directed toward Defendants and, therefore, no response is required. Defendants admit that, Celebrex® and Bextra® are in a class of drugs

that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). In addition, Defendants admit that the mechanism of action for Celebrex® and Bextra® is believed to be due to the inhibition of prostaglandin synthesis, primarily through inhibition of cyclooxygenase-2 or COX-2. Defendants deny the remaining allegations in this Paragraph of the Complaint.

24. The allegations contained in this Paragraph of the Complaint concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants deny any wrongdoing and deny the allegations in this Paragraph of the Complaint.

A. Response to Factual Background Relating to Defendant MERCK & CO., INC. ("MERCK") and Vioxx

25-97. The allegations contained in Paragraphs 25-97 of the Complaint concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Should a response be deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in these Paragraphs of the Complaint, and therefore deny the same.

B. Response to Factual Background Relating to Bextra® Defendants

98. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

99. Defendants deny that Bextra® is defective and deny the allegations in this Paragraph of the Complaint.

100. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Except as admitted herein, the Defendants deny the allegations in this Paragraph of the Complaint.

101. Defendants admit, and as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Except as admitted herein, Defendants deny the allegations in this Paragraph of the Complaint.

102. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

103. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Plaintiff fails to provide the proper context for the allegations in this Paragraph of the Complaint and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the allegations in this Paragraph of the Complaint.

104. Defendants admit that during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra®, but lack knowledge or information sufficient to form a belief as to the meaning of the phrase "a portion of the extremely lucrative consumer market," and thus deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

105. Defendants admit that Bextra® received FDA approval on November 16, 2001. Defendants further admit, and as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendant Pfizer admits that, at certain times, it has co-promoted and marketed Bextra® and co-promoted and marketed Celebrex®. Defendants admit that Bextra® and Celebrex® are in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs ("NSAIDs"). Except as admitted herein, the Defendants deny the allegations in this Paragraph of the Complaint.

106. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this Paragraph of the Complaint.

107. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this Paragraph of the Complaint.

108. Defendants state that the studies referred to in this Paragraph of the Complaint speak for themselves and any attempt to characterize them is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

109. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the studies referred to in this Paragraph of the Complaint speak for themselves and any attempt to characterize them is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

110. Defendants deny the allegations in this Paragraph of the Complaint.

111. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this Paragraph of the Complaint.

112. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this Paragraph of the Complaint.

113. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongdoing and deny the allegations in this Paragraph of the Complaint.

114. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care

and law. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this paragraph of the Complaint.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this paragraph of the Complaint.

116. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful act, deny that Bextra® caused Plaintiff injury or damages and deny the allegations in this paragraph of the Complaint.

117. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

118. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful act and deny the allegations in this paragraph of the Complaint.

119. Defendants admit that, at certain times, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

120. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that it provided FDA approved prescribing information about Bextra®. Defendants deny any misrepresentations or wrongdoing and deny the allegations in this paragraph of the Complaint.

121. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential

effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® is defective and deny the remaining allegations in this Paragraph of the Complaint.

122. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Bextra® in the United States for the indications set forth in the FDA-approved package inserts and as permitted by law. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

123. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

124. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care

and law. Defendants deny any wrongdoing and deny the allegations in this Paragraph of the Complaint.

125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or concealment, deny that Bextra® caused Plaintiff injury or damages, and deny the allegations in this Paragraph of the Complaint.

126. Defendants state that the January 2005 letter from the FDA speaks for itself and any attempt to characterize it is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

127. Defendants admit that the sale of Bextra® was voluntarily suspended in the United States market as of April 7, 2005. Defendants further state that any statements made by the FDA speak for themselves and any attempt to characterize them is denied. Defendant denies the remaining allegations in this Paragraph of the Complaint.

128. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra®, and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or misrepresentation and deny the allegations in this Paragraph of the Complaint.

129. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or misrepresentation and deny the allegations in this Paragraph of the Complaint.

130. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongdoing or concealment and deny the allegations in this Paragraph of the Complaint.

131. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful act and deny the allegations in this Paragraph of the Complaint.

132. Defendants deny the allegations in this Paragraph of the Complaint.

133. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendants deny any wrongful act, deny that Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

134. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendants deny the remaining allegations in this Paragraph of the Complaint.

135. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendant states that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this Paragraph of the Complaint.

136. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

137. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations whether Plaintiff used Bextra® and therefore deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny

that Bextra is defective, deny that Bextra caused Plaintiff injury or damages, and deny the remaining allegations of this paragraph of the Complaint.

B. Response to Factual Background Relating to Celebrex® Defendants

138. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

139. Defendants deny that Celebrex® is defective and deny the allegations in this Paragraph of the Complaint.

140. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrases "[a]t all times material hereto" and "predecessors in interest" and therefore deny the same. Defendants admit that during certain periods of time Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States, including Florida. Defendants deny the remaining allegations in this Paragraph of the Complaint.

141. The Answering Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrase "[a]t all times material hereto" and therefore deny the same. Defendants admit that during certain periods of time Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, and distributed Celebrex® in the United States, including Florida, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with its approval by the FDA. Defendants deny all remaining allegations in this Paragraph of the Complaint.

142. Defendants lack knowledge or information sufficient to form a belief as to the meaning of the phrases "[a]t all times material hereto" and "predecessors in interest" and therefore deny the same. Defendants admit that during certain periods of time, Pharmacia has co-promoted and marketed Celebrex® in the United States, including Florida to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny all remaining allegations in this Paragraph of the Complaint.

143. Defendants admit that, in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever designed, produced, manufactured, sold, resold, marketed, or distributed Celebrex®, the 2000 Monsanto is not a proper party in this suit. Defendants deny all remaining allegations in this Paragraph of the Complaint.

144. Defendants admit that, on December 31, 1998, the FDA approved Celebrex® for the treatment of the signs and symptoms of osteoarthritis and rheumatoid arthritis to be available by prescription only by healthcare providers who are by law authorized to prescribe

drugs in accordance with their approval by the FDA. Defendants further admit that during certain periods of time Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendant further admits that Pharmacia acquired Searle in 2000 and that, as a result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants further admit that during certain periods of time, Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny all remaining allegations in this Paragraph of the Complaint.

145. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant states that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any misrepresentations or wrongful acts and deny the remaining allegations in this Paragraph of the Complaint.

146. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing

information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

147. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny all remaining allegations in this Paragraph of the Complaint.

148. This paragraph contains legal contentions to which no response is required. To the extent that a response is required, Defendants deny them. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States and Florida to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States and Florida to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny wrongful conduct or misrepresentations and deny the remaining allegations in this Paragraph of the Complaint.

149. Defendants admit that the NDA for Celebrex was submitted to the FDA on June 29, 1988 by Searle. Defendants admit that on December 31, 1998, the FDA granted approval of the NDA for Celebrex. Defendants admit that, as stated in the FDA-approved labeling, Celebrex was approved for relief of the signs and symptoms of osteoarthritis and for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, Celebrex® was approved by the FDA to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") as an adjunct to usual care (e.g. endoscopic surveillance surgery). Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

150. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States and Florida to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States and Florida to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any misrepresentation or wrongful acts, and deny the remaining allegations this Paragraph of the Complaint.

151. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this Paragraph of the Complaint.

152. Defendants state that the allegations regarding "FDA updates" are vague and ambiguous and, therefore, the Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations and therefore deny the same. Defendants state that any "FDA updates" speak for themselves and any attempt to characterize them is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

153. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this Paragraph of the Complaint.

154. Defendants deny the allegations in this Paragraph of the Complaint.

155. As to the allegations in this paragraph regarding the CLASS study, Defendants state that the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny all remaining allegations contained in this Paragraph of the Complaint.

156. As to the allegations in this paragraph regarding the CLASS study, Defendants state that the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny all remaining allegations contained in this Paragraph of the Complaint.

157. As to the allegations in this paragraph regarding the CLASS study, Defendants state that the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny any misrepresentation or wrongful acts, and deny all remaining allegations contained in this Paragraph of the Complaint.

158. As to the allegations in this paragraph regarding the CLASS study, Defendants state that the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. As to the Medical Officer's Review of the CLASS Study, Defendants state that the Medical Officer's Review speaks for itself and specifically refer the Court to the Medical Officer's Review for its actual language and text. Any attempt to characterize the Medical Officer's Review is denied. Defendants deny any misrepresentation or wrongful acts, and deny all remaining allegations contained in this Paragraph of the Complaint.

159. The allegations contained in this Paragraph of the Complaint are not directed toward the Defendants and, therefore, no response is required. Should a response be deemed required, Defendants state that the referenced report speaks for itself and respectfully refer the Court to the report for its actual language and full text. Any attempt to characterize the report is denied. Defendants deny all remaining allegations in this Paragraph of the Complaint.

160. As to the allegations in this paragraph regarding the CLASS study, Defendants state that the study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. As to the allegations regarding the article, Defendants state that the article speaks for itself and respectfully refer the

Court to the article for its actual language and full text. Any attempt to characterize the article is denied. Defendants deny any misrepresentation or wrongful acts, and deny all remaining allegations contained in this Paragraph of the Complaint.

161. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Defendants state that the articles speak for themselves and respectfully refer the Court to the articles for their actual language and full text. Any attempt to characterize the articles is denied. Defendants deny any misrepresentation or wrongful acts and deny the remaining allegations contained in this Paragraph of the Complaint.

162. The allegations contained in this Paragraph of the Complaint are not directed toward the Defendants and are vague and ambiguous and assert legal conclusions, therefore, no response is required. Should a response be deemed required, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and full text. Any attempt to characterize the article is denied. Defendants deny any misrepresentation or wrongful acts and deny the remaining allegations contained in this Paragraph of the Complaint.

163. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied Defendants deny all remaining allegations contained in this Paragraph of the Complaint.

164. The allegations contained in this Paragraph are not directed toward the Defendants and are not a direct, concise averment of fact; therefore, no response is required.

Should a response be deemed required, the Defendants state that the referenced articles and reports speak for themselves, and any attempt to characterize them is denied. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

165. Defendants state that the referenced report speaks for itself and respectfully refer the Court to the report for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations contained in this Paragraph of the Complaint.

166. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint.

167. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this Paragraph of the Complaint..

168. The allegations contained in this Paragraph of the Complaint are not directed toward the Defendants and, therefore, no response is required. Should a response be deemed required, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

169. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and are not direct, concise averments of fact to which Defendants can

reasonably respond, therefore, no response is required. Should a response be deemed required, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. The Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

170. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

171. This Paragraph is not a direct, concise averment of fact to which the Defendants can reasonably respond and, therefore, no response is required. To the extent a response is deemed necessary, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

172. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants deny all remaining allegations contained in this Paragraph of the Complaint.

173. The allegations contained in this Paragraph are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Defendants state that plaintiff fails to provide the proper context for the allegations set forth in this

Paragraph and, therefore, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations and therefore deny the same. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and full text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

174. Defendants state that the referenced studies speak for themselves and respectfully refer the Court to the studies for their actual language and full text. Any attempt to characterize the studies is denied. Defendants specifically state that the referenced studies involved Vioxx®, not Celebrex®. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

175. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, Defendants state that the referenced Medical Officer's Review speaks for itself and respectfully refer the Court to the Medical Officer's Review for its actual language and full text. Any attempt to characterize the Medical Officer's Review is denied. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

176. The allegations contained in this Paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. Should a response be deemed required, the Answering Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize the study is denied. Defendants specifically state that the referenced study

involved Vioxx®, not Celebrex®. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

177. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize a study is denied. Defendants specifically state that the referenced study involved Vioxx®, not Celebrex®. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

178. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and full text. Any attempt to characterize a study is denied. Defendants specifically state that the referenced study involved Vioxx®, not Celebrex®. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

179. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations contained in this Paragraph of the Complaint.

180. Defendants specifically deny that testing and studies were grossly inadequate and deny the allegations contained in this Paragraph of the Complaint.

181. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times

adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations contained in this Paragraph of the Complaint.

182. Defendants specifically deny any "intentional[] suppress[ion]"and deny the allegations contained in this Paragraph of the Complaint.

183. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

184. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

185. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Celebrex® and therefore deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

186. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and full text. Any attempt to characterize the letters is denied. Defendants deny any wrongful conduct and deny the remaining allegations contained in this Paragraph of the Complaint.

187. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and full text. Any attempt to characterize the letter is denied. Defendants refer to the cited material for its contents. Any attempt to characterize it is denied. Defendants deny any wrongful conduct and deny all remaining allegations contained in this Paragraph of the Complaint.

188. Defendants state that the cited material speaks for itself and respectfully refer the Court to the material for its actual language and full text. Any attempt to characterize the material is denied. Defendants deny any wrongful conduct and deny the remaining allegations contained in this Paragraph of the Complaint.

189. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and

marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

190. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients 2 years and older; (4) for the relief of the signs and symptoms of ankylosing spondylitis; (5) for the management of acute pain in adults; (6) for the treatment of primary dysmenorrhea; and (7) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to usual care (e.g., endoscopic surveillance, surgery). Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this Paragraph of the Complaint.

191. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

192. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny all remaining allegations contained in this Paragraph of the Complaint.

193. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants further admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

194. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny that Celebrex® was or is dangerous and deny the allegations contained in this Paragraph of the Complaint.

195. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved

prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

196. Defendants lack knowledge or information sufficient to form a belief as to Plaintiffs' meaning of "large market share," and therefore deny the same. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

197. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

198. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and therefore deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

199. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and therefore deny the same. Defendants deny that Celebrex® caused Plaintiff injury or damages. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

200. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

201. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

202. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

203. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

204. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and therefore deny

the same. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants further state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

205. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants further state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the allegations contained in this Paragraph of the Complaint.

206. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Celebrex® and therefore deny the same. Defendants further state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants further state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury or damages. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the allegations contained in this Paragraph of the Complaint.

COUNT I

STRICT LIABILITY (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count I, Defendants hereby incorporate by reference their responses to paragraphs 1-206.

207. The allegations contained in this Paragraph concerning Vioxx and Merck are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny that Bextra® and Celebrex® were defective or unreasonably dangerous, and deny the allegations directed toward them in this Paragraph of the Complaint, including all subparts.

208. The allegations contained in this Paragraph concerning Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants deny the remaining allegations contained in this Paragraph of the Complaint.

209. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they

have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

210. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this Paragraph of the Complaint.

211. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this Paragraph of the Complaint.

212. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

213. Defendants state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny that Bextra® or Celebrex® were defective and deny the remaining allegations in this Paragraph of the Complaint.

214. The allegations contained in this Paragraph concerning Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny that Celebrex® or Bextra® caused Plaintiff injury or damages, deny that Celebrex® or Bextra® are defective, and deny the remaining allegations in this Paragraph of the Complaint.

Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

COUNT II

NEGLIGENCE (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count II, Defendants hereby incorporate by reference their responses to paragraphs 1-206.

215. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations in this Paragraph of the Complaint.

216. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint, including all subparts.

217. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

218. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants deny that

Celebrex® or Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

COUNT III

NEGLIGENT MISREPRESENTATION (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count III, Defendants hereby incorporate by reference their responses to paragraphs 1-206.

219. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny the remaining allegations in this Paragraph of the Complaint.

220. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their

FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny the remaining allegations in this Paragraph of the Complaint.

221. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

222. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

223. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® and Celebrex® are defective, and deny the remaining allegations in this Paragraph of the Complaint.

224. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants deny any wrongful conduct and deny the allegations directed toward them in this Paragraph of the Complaint.

225. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

226. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state

that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

227. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

228. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

229. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or

information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

230. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Celebrex® or Bextra® caused Plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

COUNT IV

FRAUD (as to all Defendants)

With respect to the un-numbered introductory paragraph of Count IV, the Answering Defendants hereby incorporate by reference their responses to paragraphs 1-206.

231. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

232. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing

information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

233. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

234. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether Plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

235. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

236. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint, including subparts.

237. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

238. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. This Paragraph of the

Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

239. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

240. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. This Paragraph of the Complaint contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendants admit that they have duties as are imposed by law, but deny that they have breached any such duties. Defendants deny the remaining allegations directed toward them in this Paragraph of the Complaint.

241. The allegations contained in this Paragraph concerning Merck and Vioxx are not directed toward the Defendants and, therefore, no response is required. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex®

were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

242. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this Paragraph of the Complaint.

243. The allegations contained in this Paragraph concerning Merck are not directed toward the Defendants and, therefore, no response is required. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations regarding whether plaintiff used Bextra® and Celebrex®, and therefore deny the same. Defendants state that the potential effects of Bextra® and Celebrex® were and are adequately described in their FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants further state that Bextra® and Celebrex® were and are safe and effective when used in accordance with their FDA-approved prescribing information. Defendants deny any wrongful conduct, deny that Bextra® or Celebrex® caused

plaintiff injury or damages, and deny the remaining allegations in this Paragraph of the Complaint.

The Answering Defendants deny the allegations set forth in the "Wherefore" paragraph and deny that the plaintiff is entitled to damages or costs.

Response to Demand for Trial By Jury and Costs

Defendant denies the allegations set forth in the "Demand for Trial by Jury and Costs" Paragraph and denies that the Plaintiff is entitled to an award of attorneys' fees or costs.

III.
GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® and Celebrex® are prescription medical products. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendant's labeling and warning of Bextra® and Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants,

therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drugs in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® and Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's claims should be diminished in whole or in part in the amount paid to Plaintiff by any party or non-party with whom Plaintiff has settled or may settle.

Sixth Defense

6. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendants.

Seventh Defense

7. Plaintiff's action is barred by the statute of repose.

Eighth Defense

8. Plaintiff's claims against Defendants are barred to the extent Plaintiff was

contributorily negligent, actively negligent or otherwise failed to mitigate his damages, and any recovery by Plaintiff should be diminished accordingly.

Ninth Defense

9. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Tenth Defense

10. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Eleventh Defense

11. Any injuries or expenses incurred by Plaintiff were not caused by Bextra® or Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Twelfth Defense

12. Defendants affirmatively deny that they violated any duty owed to the Plaintiff.

Thirteenth Defense

13. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® and Celebrex® are prescription medical products,

available only on the order of a licensed physician. Bextra® and Celebrex® provided adequate warnings to Plaintiff's treating and prescribing physicians.

Fourteenth Defense

14. The products at issue were not in defective conditions or unreasonably dangerous at the time they left the control of the manufacturer or seller.

Fifteenth Defense

15. Bextra® and Celebrex® were at all times material to the Complaint reasonably safe and reasonably fit for their intended use and the warnings and instructions accompanying Bextra® and Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for their approved usages.

Sixteenth Defense

16. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® and Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Seventeenth Defense

17. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® and Celebrex® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Eighteenth Defense

18. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Nineteenth Defense

19. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra® or Celebrex®.

Twentieth Defense

20. Plaintiff knew or should have known of any risk associated with Bextra® and Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twenty-first Defense

21. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-second Defense

22. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical products at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-third Defense

23. The manufacture, distribution and sale of the pharmaceutical products referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical products at issue under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-sixth Defense

26. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical products within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-seventh Defense

27. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® and Celebrex® are prescription pharmaceutical drugs and fall within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-eighth Defense

28. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical products at issue "provide[] net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Thirtieth Defense

30. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure and/or Rule 1.120 of the Florida Rules of Civil

Procedure.

Thirty-first Defense

31. Plaintiff's claims are barred because Bextra® and Celebrex® were designed, manufactured, and marketed in accordance with the state of the art at the time of manufacture per section 768.1257, Florida Statutes.

Thirty-second Defense

32. Bextra® and Celebrex® are not defective or unreasonably dangerous, and Defendants are not liable because, at the time of sale or distribution of the Bextra® and Celebrex® alleged to have been used by Plaintiff, Defendants had complied with applicable regulations of the federal Food & Drug Administration and are entitled to application of section 768.1256, Florida Statutes.

Thirty-third Defense

33. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fourth Defense

34. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-fifth Defense

35. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-sixth Defense

36. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-seventh Defense

37. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra® and Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the products' use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the products were marketed.

Thirty-eighth Defense

38. The claims asserted in the Complaint are barred because Bextra® and Celebrex® were designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Thirty-ninth Defense

39. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Fortieth Defense

40. The claims asserted in the Complaint are barred, in whole or in part, because Bextra®

and Celebrex® were not unreasonably dangerous or defective, were suitable for the purposes for which they were intended, and were distributed with adequate and sufficient warnings.

Forty-first Defense

41. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-second Defense

42. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-third Defense

43. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® and Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-fourth Defense

44. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the products complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-sixth Defense

46. The claims must be dismissed because Plaintiff would have taken Bextra® and Celebrex® even if the products' labeling contained the information that Plaintiff contends should have been provided.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred because the utility of Bextra® and Celebrex® outweighed their risks.

Forty-eighth Defense

48. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Forty-ninth Defense

49. Plaintiff's injuries and damages, if any, were proximately caused by the negligence or fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiff's recovery. Thus, Defendants are entitled to have their liability to the Plaintiff, if any, reduced as a result of the negligence or fault of said persons or entities, pursuant to the provisions of section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of Defendants' percentage of fault, taking into account the percentage of fault attributable to all other persons, whether or not a party hereto, and not on the basis of joint and several liability. The persons or entities referred to in this paragraph that are presently unknown to Defendants will be identified in a timely manner consistent with Nash v. Wells Fargo, 678 So. 2d 1262

(Fla. 1996).

Fiftieth Defense

50. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-first Defense

51. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® and Celebrex® are comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra® and Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-second Defense

52. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.
JURY DEMAND

Defendants hereby demand a trial by jury.

VI.
PRAYER

WHEREFORE, Defendants pray that Plaintiff take nothing by her suit, that Defendants

be discharged with their costs expended in this matter, and for such other and further relief to which they may justly be entitled.

s/ Edward W. Gerecke
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CERTIFICATE OF SERVICE

I CERTIFY that on May 31, 2007, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system which will send a notice of electronic filing to Brenda S. Fulmer, bfulmer@tampatriallawyers.com; C. Todd Alley, talley@tampatriallawyers.com; James D. Clark, jclark@tampatriallawyers.com; Donald Greiwe, dgreiwe@tampatriallawyers.com; Patricia E. Lowry, plowry@ssd.com; John B. T. Murray, jbmurray@ssd.com; and Maria Moncada, mmoncada@ssd.com.

s/ Edward W. Gerecke
Attorney